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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,898	07/19/2007	Yvonne Lange	047940-0280	6245

23524 7590 05/17/2011  
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EXAMINER
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YAMASAKI, ROBERT J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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05/17/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,898	<b>Applicant(s)</b> LANGE ET AL.	
	<b>Examiner</b> ROBERT YAMASAKI	<b>Art Unit</b> 1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 Jan 2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election without traverse of Group II, claims 26 and 27, is acknowledged. Claims 1-21 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 26 and 27 have been examined on the merits.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by USP No. 6,713,057 to Chatterjee, issued 30 Mar. 2004. It is noted that the effective priority date of the instant claims is the international filing date (13 April 2005). The earliest claimed priority application (US Provisional App. No. 60/561,585, filed 13 April 2004) discloses a method of modulating the cholesterol level of a cell by contacting the cell with octanol or lysophosphatidyl choline but makes no mention of modulating the cholesterol level of a cell using ceramide or diglyceride. Thus, the disclosure of US Provisional App. No. 60/561,585 does not support the full scope of claims 26 and 27 under 35 USC 112, first paragraph, as required for priority under 35 USC 119(e).

The instant claims recite a method of modulating a cholesterol level of a cell by contacting the cell with an effective amount of any of octanol, ceramide, diglyceride, lysophosphatidyl choline or a combination thereof (claim 26) and a method in which said cell is in vivo (claim 27).

Chatterjee discloses a method of modulating serum cholesterol by administering a sphingolipid, such as ceramide, as an effector of sterol regulatory element binding protein-1 (SREBP-1) (Chatterjee, col. 4, lines 18-26). SREBP-1 regulates expression of the low density lipoprotein (LDL) receptor, which facilitates internalization of LDL particles into cells and thereby increases cellular cholesterol (and decreases serum cholesterol) (Chatterjee, col. 1, lines 43-67). The sphingolipid is administered to a mammal, such as a human subject (Chatterjee, col. 7, lines 23-36). Thus, Chatterjee anticipates claims 26 and 27.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lange and Steck, J. Biol. Chem., 269(47):29371-74 (1994) (cited in Applicant's IDS of 11 Jan. 2007) discloses that lysophosphatidyl choline modulates cell cholesterol by inhibiting cholesterol esterification and stimulating cholesterol biosynthesis (Lange and Steck, p. 29371, right column, 1st full para.).

JP 63-104917 to Murata et al. discloses an oral composition for lowering blood cholesterol comprising a diglyceride of highly unsaturated fatty acids. An English translation has been ordered but is not currently available.

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It is noted that the cited prior art does not teach or fairly suggest a method of modulating cell cholesterol by contacting the cell with octanol.

The abstract of the disclosure is objected to because it is not directed to the elected invention. Correction is required. See MPEP § 608.01(b).

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT YAMASAKI whose telephone number is (571)270-5467. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

/Robert Yamasaki/  
Examiner, Art Unit 1657